

EPA Jacket 432-1522

Vol.2

MATERIAL TO BE ADDED TO JACKET

REG #: 432 1522

Description: Amendment to add tank mix to the
Supplemental and registered product labels

if applicable, check all that are attached:

<input checked="checked" type="checkbox"/>	new stamped accepted label <i>only</i>	Send to CSC
<input type="checkbox"/>	new CSF	
<input type="checkbox"/>	notification	
<input type="checkbox"/>	other:	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: Menyon Adams Date: FEB 07 2014

Phone: (703) 347-8496 Division: BPPD



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 07 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Richard Gorrell
Regulatory Manager
Bayer Environmental Science
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: ESTC006A
EPA Registration No. 432-1522
Label Amendment to add tank mix partners to the supplemental and registered product labels
Decision #'s: 485177 and 486896
Application Dated: November 14, 2013

Dear Mr. Gorrell:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is **acceptable** provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit three (3) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(b). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions contact Ms. Menyon Adams at 703-347-8496 or by email at: adams.menyon@epa.gov. A stamped copy of the label is enclosed for your records.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda A. Hollis", is written over the word "Sincerely,".

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

ES TC006A

(ABN: FIATA™; FIATA™ StressGard™)

A SYSTEMIC FUNGICIDE AND BOOSTER OF PLANT DEFENSE MECHANISMS THAT PROMOTES DROUGHT TOLERANCE AND HELPS CONTROL LISTED DISEASES OF TURFGRASS

ACTIVE INGREDIENT: Mono- and di-potassium salts of phosphorous acid *25.85%
OTHER INGREDIENTS: 74.15%
TOTAL: 100.00%

* Contains 2.64 lb active ingredient per gal; equivalent to 1.73 lb phosphorous acid per gal (17.0% w/w)

EPA Reg. No. 432-1522

EPA Est. No. _____

KEEP OUT OF REACH OF CHILDREN

For MEDICAL and TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information, Call 1-800-331-2867

FIRST AID

If swallowed:

- Immediately call a poison control center or doctor for treatment advice.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Have person sip a glass of water if able to swallow.
- Do not give anything by mouth to an unconscious person.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS

For Terrestrial Uses

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of rinsate or equipment washwaters.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear long-sleeved shirt and long pants, and shoes plus socks.

Follow manufacturer's instructions for cleaning/maintaining personal protective equipment (PPE). If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROL STATEMENT

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

ACCEPTED

FEB 07 2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 432-1522

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove PPE clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval of 4 hours.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: coveralls, waterproof gloves, shoes plus socks, and protective eyewear.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Do not enter treated areas without protective clothing until sprays have dried.

PLANT HEALTH RESPONSES

ES TC006A, when applied at the prescribed rates and intervals, promotes healthier roots, and increases plant drought tolerance and improves plant water utilization. This leads to a reduction in the need for hand watering and a general saving of water use. The resulting improvement in function of these healthier roots leads to more efficient uptake of plant nutrients. Improving cell turgidity results in a healthier and sturdier plant structure, reducing the impact of traffic or mechanical damage. These effects are consistent with the properties of anti-oxidants. A property of ES TC006A is to act as an inducer of systemic resistance in plants resulting in production of plant metabolites responsible for improving plant processes and increasing resistance to diseases.

Cool-season grasses such as tall fescues, bluegrasses, and bentgrasses are prone to damage during summer heat and summer decline leading to reduced root mass in the summer months. Turf treated with ES TC006A retains turf quality through summer stress by alleviating plant stresses, enhancing disease resistance through induced system resistance, and protecting the plant from the adverse effects of solar radiation.

Warm-season grasses, such as Bermudagrass and Zoysiagrass, influenced by the effects of insufficient sunlight during the spring and fall, are prone to losing chlorophyll and premature senescence. ES TC006A reduces the negative effects on plant growth promoting earlier spring green-up, turf fill-in, and extended turf quality in the fall.

PRODUCT INFORMATION

ES TC006A must be applied as a foliar spray. Apply ES TC006A with sufficient water volumes for adequate coverage of foliage, according to the turf growth stage.

STAINING PRECAUTION

This product may cause staining. Avoid off-target sites such as sidewalks, patios, driveways, pavers, or similar materials. Do not enter treated areas until spray has dried. Rinse spray equipment thoroughly with warm water and detergent.

MIXING INSTRUCTIONS

1. Fill the spray tank with 1/4 - 1/2 of the required volume of water before adding ES TC006A.
2. Add ES TC006A slowly to the tank and agitate by hydraulic or mechanical means.
3. Continue to fill the tank with water to the desired volume while agitating.
4. Continue agitation when applying.

COMPATIBILITY

ES TC006A is compatible with most products used on turf; however, turfgrass sensitivity to these mixtures may vary. In particular, certain foliar fertilizers and copper products may not be compatible with ES TC006A and the combined use may cause phytotoxicity to certain plants. If these combinations or others have not been used before, do not tank mix without first testing the mixture's compatibility nor apply it without assessing its safety to the turfgrass (phytotoxicity).

To determine the compatibility of ES TC006A with other products, use a jar compatibility test. Add the correct proportions of each product and the appropriate quantity of water to clean container, thoroughly mix, then let stand for 3 - 5 minutes. If the mixture remains in solution or can be remixed readily, the products are considered compatible. To determine if a combination is phytotoxic to a specific turf, spray a small area and then evaluate 3 - 7 days later for visual effects.

TURF

ES TC006A is a systemic fungicide and booster of plant defense mechanisms that is used for the suppression of Pythium blight and damping-off diseases of turfgrass on sod farms, golf courses, sport fields, parks, residential and commercial sites. Begin preventative applications when conditions first favor disease and repeat at prescribed intervals. Use higher rates under severe disease conditions.

DISEASE	APPLICATION METHOD	RATE	APPLICATION PROGRAM
Pythium	Foliar Spray	5 to 15 fl. oz./1,000 sq. ft.	Apply approved amount in 1 to 5 gal of water per 1,000 square feet. Thoroughly wet the foliage. Apply at 14 to 28 day intervals as needed. Do not mow or irrigate treated area until sprays have completely dried.

ES TC006A has a plant health component that is used for the prevention or alleviation of stress from drought, solar radiation and other oxidative processes on turfgrasses on sod farms, golf courses, sport fields, parks, residential and commercial sites. Begin preventative applications prior to the occurrence of adverse weather conditions or before watering restrictions are imposed and repeat at prescribed intervals. Use higher rates under severe drought conditions or irrigation reduction. ES TC006A does not replace the use of soil amending adjuvants for soil hydrophobicity and should be used in conjunction with best turf management practices.

DROUGHT TOLERANCE	APPLICATION METHOD	RATE	APPLICATION PROGRAM
Irrigation reduction of 20 to 50% or during periods of low rainfall for up to 4 to 9 weeks	Foliar Spray	5 to 15 fl. oz./1,000 sq. ft.	Apply approved amount in 1 to 5 gal of water per 1,000 square feet. Thoroughly wet the foliage. Apply at 14 to 28 day intervals as needed to fairway or lawn height cut turf. Do not mow or irrigate treated area until sprays have completely dried.

Optimal results for overall turfgrass health are achieved when using the following prescribed combination or a sequential applications in a preventative program for disease control.

PRESCRIBED TANK-MIXTURES	RATE FL OZ / 1000 SQ. FT
Fiata	4.4 to 6
+ Tartan®, or	1 to 2
+ Interface®, or	3 to 5
+ Bayleton®, or	0.5 to 1
+ Mirage™ StressGard	1 to 2
Applications Make applications of the fungicide as prescribed on the specific fungicide label. Use in a minimum spray water volume of 2 gal per 1000 sq. ft. Use lower rates of Fiata for shorter spray intervals.	

The addition of 4.5 to 6 fl oz of Fiata to any product containing trinexapac- ethyl such as Primo MAXX at prescribed label rates for turfgrass growth regulation enhances the level of tolerance to stress conditions, and the consistency of turf greenness.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE:

Keep this product in containers stored upright and secured with the original closure. Do not store this product near heat sources. If transfer to another container becomes necessary, ensure that the container is clearly labeled, the container is a type suitable for the product, and is clean and free of other materials.

PESTICIDE DISPOSAL:

Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

Rigid, Non-refillable containers less than 5 gallons

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable containers - Do not reuse or refill this container. Refer to Bottom Discharge IBC or Top Discharge IBC, Drums, Kegs information as follows.

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. - Snyder 120 Next Gen, Bonar B120, Drums, Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties, and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties, and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and should be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of BAYER CROPSCIENCE is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

BATH CODE: _____

NET CONTENTS: [Various (1 gal to 50 gal)]

PRODUCED FOR



Bayer Environmental Science

A Division of Bayer CropScience, LP
PO Box 12014 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

ES TC006A (PENDING) 11/12/2013

APPENDIX: Optional Marketing Claims:

Better drought tolerance
Improved water utilization
Saves water expenses
Reduce need for hand watering
Retain turf quality through summer stress
Reduces plant stress thus requiring less watering
Reduce afternoon syringing [note: syringing is a light application of water to turf foliage]
Enhanced disease resistance from a healthier root system
Provides enhanced plant health to minimize water uptake requirements
Drought stress protection
Water optimizing formula
Innovative formula reduces water needs
Turf grass exits dormancy for faster green-up
Provides more efficient root uptake of surrounding soil moisture
Reduce irrigation budget by [XX]%
Reduce cost of watering by [XX]%
Reduce irrigation needs by [XX]%
Greener lawn with [XX]% water requirements
Cut your water bill [XX %]



Bayer Environmental Science

A Division of Bayer CropScience LP
2 T. W. Alexander Drive
Research Triangle Park, NC 27709
1-866-99Bayer (1-866-992-2937)

FIATA™STRESSGARD™

EPA Reg. No. 432-1522

For Use On: Turfgrasses

*This supplemental label expires xxx and must not be
used or distributed after this date*

Supplemental Label

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. Read this label and the product package label before using this product. This Supplemental Label must be in the possession of the user at the time of pesticide application. Follow all applicable directions, restrictions, Worker Protection Standard requirements, and precautions on the product label for FIATA attached to the container.

USE DIRECTIONS SPECIFIC FOR TURFGRASSES

Optimal results for overall turfgrass health are achieved when using the following prescribed combination or a sequential applications in a preventative program for disease control.

PRESCRIBED TANK-MIXTURES	RATE FL OZ / 1000 SQ. FT
Fiata	4.4 to 6
+ Tartan®, or	1 to 2
+ Interface®, or	3 to 5
+ Bayleton®, or	0.5 to 1
+ Mirage™ StressGard	1 to 2
Applications Make applications of the fungicide as prescribed on the specific fungicide label. Use in a minimum spray water volume of 2 gal. per 1000 sq. ft. Use lower rates of Fiata for shorter spray intervals.	

The addition of 4.5 to 6 fl oz of Fiata to any product containing trinexapac-ethyl such as Primo MAXX at prescribed label rates for turfgrass growth regulation enhances the level of tolerance to stress conditions, and the consistency of turf greenness.

This supplemental label expires xx, 201x and must not be used or distributed after this date.
 For **MEDICAL** And **TRANSPORTATION** Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577
 For **PRODUCT USE** Information Call 1-800-331-2867
As with any crop-protection product, always read and follow label directions.
For additional information call toll-free 1-800-331-2867.

Fiata and Mirage are trademarks of Bayer. Tartan, Interface, and Bayleton are registered trademarks of Bayer. Primo MAXX is registered trademark of a Syngenta Group Company.

(PENDING) 10/31/13

ACCEPTED

FEB 07 2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 432-1522



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 07 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Richard Gorrell
Regulatory Manager
Bayer Environmental Science
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: ESTC006A
EPA Registration No. 432-1522
Label Amendment to add tank mix partners to the supplemental and registered product labels
Decision #'s: 485177 and 486896
Application Dated: November 14, 2013

Dear Mr. Gorrell:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is **acceptable** provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit three (3) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(b). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions contact Ms. Menyon Adams at 703-347-8496 or by email at: adams.menyon@epa.gov. A stamped copy of the label is enclosed for your records.

Sincerely,

CONRAD H. ELLIS, Chief

SYMBOL	751P			Biochemical Pesticides Branch		
SURNAME	Adams			Biopesticides and Pollution		
DATE	02/04/14			Prevention Division (7511P)		

BPPD Label Amendment Checklist

Fast Track ☒ and PRIA Actions B650 ☐, B680 ☐, B661 ☐, B730 ☐, B890 ☐ & B900 ☐

EPA Reg. No.: 432-1522

RAL: 11/16/12

Application Date: 11/14/12

#	Checklist Item	Yes	No
1.	Application Form (EPA Form 8570-1) - signed & complete, including package type? IF NO, STOP! Call applicant and have them correct application and resubmit.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2.	Final printed labeling received for previous action? IF NO, STOP! E-mail applicant and request final printed labeling (FPL).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.	Does the registration notice have terms/conditions (ex: storage stability data)? If so have the terms/conditions been met?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4.	If new use sites are being added, are they subject to OPP's process for public involvement in pesticide registration actions?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.	Data and Data Matrix present. (EPA Form 8570-35) NA <input checked="" type="checkbox"/> If Fast Track, check to see if original registration supported by data, formulators exemption, etc.	<input type="checkbox"/>	<input type="checkbox"/>
a.	Using Selective Method? [IF NO, SKIP to item 4 and note that data matrix should be used for the cite-all method to indicate the companies to whom offers of compensation were made.]	<input type="checkbox"/>	<input type="checkbox"/>
b.	Complete Data Matrix supporting both the product registration and the proposed amendment. Minimum Data Matrix for registration includes: Product specific Acute Toxicity and Product Chemistry data, plus Efficacy data for public health pests claimed on label.	<input type="checkbox"/>	<input type="checkbox"/>
c.	Adequate product specific data?	<input type="checkbox"/>	<input type="checkbox"/>
d.	Registered source used for active ingredient? IF YES, SKIP to ITEM 4. (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) IF NO or if use not supported by registered source, generic data is necessary.	<input type="checkbox"/>	<input type="checkbox"/>
e.	If new data submitted: data passed PR Notice 86-5 for formatting and MRID # assigned?	<input type="checkbox"/>	<input type="checkbox"/>
f.	Public copy of Data Matrix provided? (PRN 98-5)	<input type="checkbox"/>	<input type="checkbox"/>
6.	Certification with Respect to Citation of Data present. (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [If no data are required or submitted, a Certification with Respect to Citation of Data form isn't needed. This is often true for minor amendments.] NA <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a.	Did applicant check a Method of Support?	<input type="checkbox"/>	<input type="checkbox"/>
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?	<input type="checkbox"/>	<input type="checkbox"/>
c.	Is the form signed and dated?	<input type="checkbox"/>	<input type="checkbox"/>
d.	Check form and Data Matrix. Are Exclusive Use data cited from other sources? IF YES, is the required authorization letter included in application? NA <input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Label(s) Review <i>11/16/12</i> Date of Label Review: 02/03/14	<input type="checkbox"/>	<input type="checkbox"/>
a.	Label(s) in conformance with current <i>Label Review Manual</i> and appropriate REDS.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers). Acceptable efficacy studies support public health pests claimed on label.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c.	Nominal concentration of active ingredient shown in ingredients statement.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
e.	Storage and disposal instructions agree with container types listed on application form.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
f.	Unique Product Name for Same Company (Check OPPIN).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? IF YES, RAL must evaluate label use directions for compliance with 40 CFR 180.1071.	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Receipt for Section 3

S: 943693

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Company: 432 BAYER ENVIRONMENTAL SCIENCE

Billable: ☐ Yes ☒ No

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 432-1522

Product Name: ES TC008A

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 14-Nov-2013

Front End Date: 15-Nov-2013

FFS Due Date:

OPP Target Date:

Fast Track: ☐

Receipt Description: AMENDMENT

Form A: ☐

OPP Rec'd Date: 15-Nov-2013

Risk Manager Send Date: 20-Nov-2013

Negotiated Due Date:

New Ingredient: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content	Des
Paper Label	

View/Edit

Completed

RECEIVED
JAN 22 2014
MOSAM

Bryceland, Andrew

From: Mike Gorrell [mike.gorrell@bayer.com]
Sent: Thursday, January 16, 2014 12:27 PM
To: Bryceland, Andrew
Subject: FW: Fiata Stressgard (432-1522) Supplemental Label Submission Package
Attachments: SubmPackageEPA13RMG1114FiataStressGSupplem.pdf

I still put Andy instead of Andrew. Just got back in the office to resend.

From: Mike Gorrell
Sent: Thursday, January 16, 2014 9:05 AM
To: bryceland.andy@epa.gov
Subject: Fiata Stressgard (432-1522) Supplemental Label Submission Package

See attached Subm Packet

Thanks very much for helping out on this. As I understand from our telephone conversation this morning, the supplemental label was never delivered to you for review from the front desk. However, you have generously proposed to have Menyon Adams review it along with the label amendment. The supplemental label will take precedence over the label amendment.

Again, I want to thank you for your help.

The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.

For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>

Bayer CropScience



November 14, 2013

EPA13RMG1114FiataStressGSupplem
FedEx

Ms. Menyon Adams
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: Fiata Stressgard (432-1522): Supplemental label to Add the Use of Selected Tank Mix Partners

Dear Ms. Adams:

Bayer Environmental Science (BES) is submitting a supplemental label for the alternate brand name Fiata StressGard to add tank mix partners to the label for optimal overall turfgrass health in a preventative program for disease control. This letter contains the following information:

- 8570-1 Application Form
- 5 copies of the supplemental label

If you have any questions, contact me at (919) 549-2423 or email me at mike.gorrell@bayercropscience.com.

Sincerely,

Richard M. Gorrell
Manager, Registrations

Incl.

Cc Karen Shearer (Bayer)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 432-1522	2. EPA Product Manager Menyon Adams	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ESTC006A ABN:Fiata;Fiata StressGard	PM#	
5. Name and Address of Applicant (Include ZIP Code) Bayer Environmental Science P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Supplemental Label to Add Tank Mix Partners

Section - III

1. Material This Product Will Be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 gallon		5. Location of Label Directions <input type="checkbox"/> Container label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Richard M. Gorrell		Title Regulatory Manager		Telephone No. (Include Area Code) (919) 549-2423	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Richard M. Gorrell</i>		3. Title Regulatory Manager			
4. Typed Name Richard M. Gorrell		5. Date November 14, 2013			



Bayer Environmental Science

A Division of Bayer CropScience LP
2 T. W. Alexander Drive
Research Triangle Park, NC 27709
1-866-99Bayer (1-866-992-2937)

FIATA™STRESSGARD™

EPA Reg. No. 432-1522

For Use On: Turfgrasses

*This supplemental label expires xxx and must not be
used or distributed after this date*

Supplemental Label

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. Read this label and the product package label before using this product. This Supplemental Label must be in the possession of the user at the time of pesticide application. Follow all applicable directions, restrictions, Worker Protection Standard requirements, and precautions on the product label for FIATA attached to the container.

USE DIRECTIONS SPECIFIC FOR TURFGRASSES

Optimal results for overall turfgrass health are achieved when using the following prescribed combination or a sequential applications in a preventative program for disease control.

PRESCRIBED TANK-MIXTURES	RATE FL OZ / 1000 SQ. FT
Fiata	4.4 to 6
+ Tartan®, or	1 to 2
+ Interface®, or	3 to 5
+ Bayleton®, or	0.5 to 1
+ Mirage™ StressGard	1 to 2
Applications Make applications of the fungicide as prescribed on the specific fungicide label. Use in a minimum spray water volume of 2 gal. per 1000 sq. ft. Use lower rates of Fiata for shorter spray intervals.	

The addition of 4.5 to 6 fl oz of Fiata to any product containing trinexapac-ethyl such as Primo MAXX at prescribed label rates for turfgrass growth regulation enhances the level of tolerance to stress conditions, and the consistency of turf greenness.

This supplemental label expires xx, 201x and must not be used or distributed after this date.
For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-800-331-2867
As with any crop-protection product, always read and follow label directions.
For additional information call toll-free 1-800-331-2867.

Fiata and Mirage are trademarks of Bayer. Tartan, Interface, and Bayleton are registered trademarks of Bayer. Primo MAXX is registered trademark of a Syngenta Group Company.

(PENDING) 10/31/13

S: 943694

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 432 BAYER ENVIRONMENTAL SCIENCE



Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 432-1522 Product Name: ES TC006A

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 14-Nov-2013

OPP Rec'd Date: 15-Nov-2013

Front End Date: 15-Nov-2013

Risk Manager Send Date: 20-Nov-2013

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Receipt Content	Det
Paper Label	
View/Edit	

485177
485177

Due
02/13/14

Mcnyon

12/14/14

RECEIVED
DEC 03 2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 20, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MARGARET CHERNY
BAYER ENVIRONMENTAL SCIENCE
A DIVISION OF BAYER CROPSCIENCE LP
2 T. W. ALEXANDER DRIVE, PO Box 12014
RESEARCH TRIANGLE PARK, NC 27709-

PRODUCT NAME: ES TC006A
COMPANY NAME: BAYER ENVIRONMENTAL SCIENCE
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 432-1522
EPA RECEIPT DATE: 11/15/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-6928.

Sincerely,

A handwritten signature in black ink, appearing to be "S", is written over a horizontal line.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



Fee for Service

{943694K~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☒ BPPD
- ☐ RD

Risk Mgr. 91

Receipt No.

S-

943694

EPA File Symbol/Reg. No.

432-1522

Pin-Punch Date:

11/15/2013

✓ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Andrew Bryceland

Date: 11/20/13

Remarks:

Bayer CropScience



November 14, 2013

EPA13RMG1114FiataAmend

FedEx

Ms. Menyon Adams
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: ESTC006A (432-1522) ABNs - Fiata and Fiata Stressgard: Label Amendment and Supplemental label to Add Revised Use Instructions

Dear Ms. Adams:

Bayer Environmental Science (BES) is amending its ESTC006A label to add tank mix partners to the label for optimal overall turfgrass health in a preventative program for disease control. In addition, the same language is being added to a supplemental label in order for the product to be used in this manner once approved. The supplemental label is being submitted under a separate submission.

This letter contains the following information:

- 8570-1 Application Form
- 5 copies of the revised label (1 copy shaded in yellow)

If you have any questions, contact me at (919) 549-2423 or email me at mike.gorrell@bayercropscience.com.

Sincerely,

Richard M. Gorrell
Manager, Registrations

Incl.

Cc Karen Shearer (Bayer)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 432-1522	2. EPA Product Manager Menyon Adams	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ESTC006A	PM#	
5. Name and Address of Applicant (Include ZIP Code) Bayer Environmental Science P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label Amendment to Add Tank Mix Partners

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 gallon		5. Location of Label Directions <input type="checkbox"/> Container label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Richard M. Gorrell		Title Regulatory Manager		Telephone No. (include Area Code) (919) 549-2423	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Richard M. Gorrell</i>		3. Title Regulatory Manager			
4. Typed Name Richard M. Gorrell		5. Date November 14, 2013			

S: 343693

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 432 BAYER ENVIRONMENTAL SCIENCE



Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 432-1522

Product Name: ES TC006A

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 14-Nov-2013



OPP Rec'd Date: 15-Nov-2013



Front End Date: 15-Nov-2013



Risk Manager Send Date: 20-Nov-2013



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Des

Paper Label

View/Edit

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 20, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MARGARET CHERNY
BAYER ENVIRONMENTAL SCIENCE
A DIVISION OF BAYER CROPSCIENCE LP
2 T. W. ALEXANDER DRIVE, PO Box 12014
RESEARCH TRIANGLE PARK, NC 27709-

PRODUCT NAME: ES TC006A
COMPANY NAME: BAYER ENVIRONMENTAL SCIENCE
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 432-1522
EPA RECEIPT DATE: 11/15/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-6928.

Sincerely,

A handwritten signature in black ink, appearing to be "S. [unclear]".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



Fee for Service

{943893M~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☒ BPPD
- ☐ RD

Risk Mgr. 91

Receipt No.

S- 943893

EPA File Symbol/Reg. No.

432-1522

Pin-Punch Date:

11/15/2013

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Andrew Byceland

Date: 11/20/13

Remarks:

Bayer CropScience



November 14, 2013

EPA13RMG1114FiataStressGSupplem
FedEx

Ms. Menyon Adams
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: Fiata Stressgard (432-1522): Supplemental label to Add the Use of Selected Tank Mix Partners

Dear Ms. Adams:

Bayer Environmental Science (BES) is submitting a supplemental label for the alternate brand name Fiata StressGard to add tank mix partners to the label for optimal overall turfgrass health in a preventative program for disease control. This letter contains the following information:

- 8570-1 Application Form
- 5 copies of the supplemental label

If you have any questions, contact me at (919) 549-2423 or email me at mike.gorrell@bayercropscience.com.

Sincerely,

Richard M. Gorrell
Manager, Registrations

Incl.

Cc Karen Shearer (Bayer)



United States
Environmental Protection Agency
Washington, DC 20460

☐
☐
☒

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 432-1522	2. EPA Product Manager Menyon Adams	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ESTC006A ABN:Fiata;Fiata StressGard	PM#	
5. Name and Address of Applicant (Include ZIP Code) Bayer Environmental Science P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Supplemental Label to Add Tank Mix Partners

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 gallon		5. Location of Label Directions <input type="checkbox"/> Container label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Richard M. Gorrell		Title Regulatory Manager		Telephone No. (include Area Code) (919) 549-2423	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Data Application Received (Stamped)
2. Signature <i>Richard M. Gorrell</i>		3. Title Regulatory Manager			
4. Typed Name Richard M. Gorrell		5. Date November 14, 2013			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 04 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Richard M. Gorrell
Bayer Crop Science
2 T.W. Alexander Drive
RTP, NC 27709

Subject: ES TC006A
EPA Registration No. 432-1522
Storage Stability (OCSPP Guideline No. 830.6317) and Corrosion Characteristics (OCSPP Guideline No. 830.6320)
Decision # 481004
Application Dated: June 28, 2013

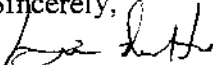
Dear Mr. Gorrell:

The Storage Stability and Corrosion Characteristics Guideline study (OPPTS 830.6317 and OPPTS 830.6320) referred to above submitted in response to the terms and conditions of registration is **unacceptable**. In order for the studies to be acceptable, you must provide the following information:

1. The number of replications used at each sampling interval (including raw data),
2. A clarification of whether refrigerated samples were analyzed for active ingredient content,
2. The temperature ranges at which the samples were stored under ambient (warehouse) and refrigerated conditions, and
4. A method validation

If you have any questions contact Ms. Menyon Adams at 703-347-8496 or by email at: adams.menyon@epa.gov.

Sincerely,


Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Chemical Safety and Pollution Prevention

MEMORANDUM

08/02/2013

SUBJECT: Storage Stability and Corrosion Characteristics Studies for ES TC006A
Containing 16.8% Phosphorous Acid as its Active Ingredient.

EPA Reg. No.: 432-1522
Chemical Class: Biochemical
PC Code : 076416
DP No : 413879
Decision No. : 481004
MRID No.: 49162901

FROM: Russell S. Jones, Ph.D., Senior Biologist /S/ 08/02/2013
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

A handwritten signature in black ink, appearing to read "Russell S. Jones", is written over the date and name in the "FROM:" field.

TO: Menyon Adams, Regulatory Action Leader /S/ 08/02/2013
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

On behalf of Bayer CropScience., R. M. Gorrell has submitted a combined Storage Stability and Corrosion Characteristics Studies for ES TC006A (EPA Reg. No. 432-1522) according to OCSPP Test Guidelines 830.6317 and 830.6320 (MRID 49162901).

RECOMMENDATIONS AND CONCLUSIONS

The studies demonstrate that the product is apparently stable in storage in its normal containers for up to 12 months under normal conditions of storage. In addition to these results, no corrosion was noted on any of the containers. However, certain experimental details that could have impact on the quality of the study were not provided. Therefore, the studies are considered **SUPPLEMENTAL, but Upgradeable.**

To upgrade the studies to Acceptable, the registrant must provide information regarding:

1. The number of replications used at each sampling interval (including raw data),
2. A clarification of whether refrigerated samples were analyzed for active ingredient content,
2. The temperature ranges at which the samples were stored under ambient (warehouse) and refrigerated conditions, and
4. a method validation

STUDY SUMMARIES

The submitted study contains the final data for a combined, one-year Storage Stability and Corrosion Characteristics study in typical packaging material for the end-use product (EP) ES TC006A (OCSPG Guidelines 830.6317 and 830.6320).

Storage Stability and Corrosion Characteristics Study Design (MRID 449162901)

The Storage Stability and Corrosion Characteristics study report contains data on the active ingredient in the EP ES TC006A (EPA Reg. No. 432-1522) collected after storage of up to 12 months at normal and refrigerated conditions. Storage stability was determined by titration. Corrosion Characteristics were determined by visual observations. The study was GLP compliant and conducted according to OCSPG 830.6317 and 830.5320 Test Guidelines.

Active ingredient content was determined by titration with 0.1N sodium thiosulfate in the presence of 0.05 M iodine and starch indicator solution. The volume of titrant used to cause disappearance of blue/black color was used to calculate the active ingredient content. Complete details of the analytical method and all calculations are contained in MRID 449162901, pp. 11-12.

Samples of test substance were placed into storage in sealed high-density polyethylene (HDPE) bottles at the initiation of this study on March 3, 2012. The samples are stored under ambient warehouse conditions (temperature range not specified) and under refrigeration at no more than 10 °C, except for one week beginning at 09/23/2012. There was no apparent effect on the study results. All containers were weighed and observed for the physical condition at the beginning of the study and were examined again at each subsequent sampling point. Samples were analyzed and containers observed for physical changes at 0, 3, 6, 9, and 12 months of storage.

RESULTS: There were minor declines in active ingredient % after 12 months storage under ambient (warehouse) conditions and no apparent corrosion of the packaging under ambient and refrigerated storage conditions (see Tables in MRID 449162901, pp. 8-10).

DEFICIENCIES: It is unclear how many replications, if any, were used at each sampling interval. Similarly, it is unclear if any samples were analyzed from the refrigerated samples. In addition, the temperature ranges at which samples were stored under ambient (warehouse) and refrigerated conditions were not specified. A method validation was not provided.

CONCLUSIONS

The studies demonstrate that the product is apparently stable in storage in its normal containers for up to 12 months under normal conditions of storage. In addition to these results, no corrosion was noted on any of the containers. However, certain experimental details that could have impact on the quality of the study were not provided. Therefore, the studies are considered **SUPPLEMENTAL, but Upgradeable.**

To upgrade to Acceptable, the registrant must provide information regarding the actual temperature ranges under which samples were stored under ambient and refrigerated conditions, and the number of replications, if any, used at each sampling interval,

cc: R. S. Jones, M. Adams, BPPD Subject File/IHAD
R. S. Jones, Ph.D., Sr. Scientist, FT, OPY: 08/02/2013



Bayer CropScience

June 27, 2012

EPA13RMG0627ESTC006A_SSCC
FEDEX

Ms. Menyon Adams
U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Bayer CropScience
2 T.W. Alexander Drive
RTP, NC 27709
Phone : 919.549.2000

RE: ESTC006A(432-1522) ABN - Fiata: Submitting Storage Stability And Corrosion Characteristics Studies (OCSP 830.6317 and 830.6320)

Dear Ms. Adams:

Bayer Environmental Science (BES) is submitting the EPA mandated Storage Stability and Corrosion Characteristics studies from the Agency's label approval letter dated May 29, 2012.

The following information accompanies this letter:

- 8570-1 application form
- 49162901** 3 copies of the combined studies report (Packaging Storage Stability and Corrosion Characteristics of ES TC006A)

If you have any questions, contact me at (919) 549-2423 or email me at mike.gorrell@bayercropscience.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Gorrell".

Richard M. Gorrell
Manager, Registrations

Incl.
Cc Karen Shearer